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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,450	10/24/2001	Brian Craig Lee	10010463 - 1	2047

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EXAMINER	
JOYNES, ROBERT M	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/028,450	LEE ET AL.	
	Examiner	Art Unit	
	Robert M. Joynes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-20,23,24,27,54 and 73-85* is/are pending in the application.

4a) Of the above claim(s) *9,21,22,25,26,28-53 and 55-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-20,23,24,27,54 and 73-85* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/02/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicants' Amendment and Response filed on February 19, 2004 and Information Disclosure Statement filed on January 2, 2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 73 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The dependent claim recites that the ingestible sheet further comprises a *water-expandable foam disposed on or within the ingestible sheet.* When carefully reviewing the Specification, the Examiner found that applicants define the foam as material such as oxidized regenerated cellulose (Surgicel) and a porcine derived gelatin powder (Gelfoam) (See Page 7 of the instant Specification). Both of these products are used as a hemostatic device to absorb blood and other bodily fluids and to facilitate clotting. Further, neither is taught as ingestible. The specification sheets for the devices teach that the products should be used to achieve hemostasis and as little as the product as possible should be used. In the case of Surgicel, the product should not even be left in place. It should be removed as soon as the bleeding has ceased (See the Specification Sheet for the products for further details). Therefore, the Specification of the instant

application does enable one skilled in the art to prepare an ingestible sheet for delivery of a bioactive fluid where the sheet includes a water-expandable foam as described in the Specification. The additional ingredient recited in the claims is not known for such function and is not taught to be ingestible for carrying a drug but rather is known as a clotting composition to stop bleeding.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 73 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the Examiner how the sheet of the instant claim remains ingestible when an ingredient is added that is not known to be ingestible or known for carrying a bioactive fluid but rather is known for stopping bleeding. It is unclear to the Examiner why one skilled in the art would add a clotting agent to an ingestible sheet that contains a bioactive fluid. Clarification is suggested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8, 10-20, 23, 24, 27, 54 and 75-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carden, Jr. et al. (US 6086942) in combination with Stewart (WO 95/01735). Carden teaches a method of depositing a radioactive fluid onto a surface of a substrate as drops from a fluid-jet print head (Col. 2,lines 42-54; Col 14, line 15 – Col. 15, line 60)). The substrate may be a flat, convex or concave sheet (Col. 4, lines 11-24). The substrate is further coated with a sealing layer or layers (Col. 8, lines 50-65). The substrate can also include the simultaneous application of colored ink and radioactive material to mark or code the outer surface of the substrate (Col. 16, lines 17-26). Further, Carden teaches the bioactive fluid printed on the sheet can be tailored by changing the position or amount of the radioactive material (Col. 6, lines 10-12).

Stewart teaches a method of printing on edible film or sheets (Page 9, line 19 – Page 17). The printing may include special messages, pictures, and/or drawings or other source material (Page 19, lines 1-7). The edible sheet can be used in a manner similar to normal paper thereby making available any printing machine, specifically an ink jet printer ((Page 19, lines 1-7; Page 20, lines 20-25).

Carden does not expressly teach the substrate as an edible substrate but does teach that the sheet is biodegradable, degradable by the body by solubilization, by macrophage activity or by other naturally present digestive processes. Stewart does

not expressly teach that the fluid in the ink jet cartridge is bioactive. Neither reference teaches the gradient composition recited in instant claims 9-15. Carden does teach that position of the bioactive fluid can be tailored on the sheet as well as the amount of the fluid to be administered. Further, Carden teaches that the fluid distributed on the sheet can be symmetrical or asymmetrical (Col. 6, lines 1-20).

When Carden is read in view of Stewart, it would be obvious to print a bioactive fluid on an edible or ingestible sheet or substrate. Carden teaches the printing of a radioactive (bioactive) fluid onto a sheet that is later used in the body through the aid of printing equipment. The form of the sheet is biodegradbale. Stewart teaches that edible films are known and printed on with edible inks and flavorings that convey a message or picture.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to print a bioactive fluid on an edible or ingestible sheet that further includes writing or a message that is achieved with edible colored ink.

One of ordinary skill in the art would have been motivated to do this to produce a product that delivers precise amounts of the bioactive fluid that are specific to the prescription required for a particular patient or application.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

When Stewart is read in view of Carden, it would have been obvious to incorporate a bioactive agent in the edible fluid to be deposited on the edible sheet or film. The teachings of each reference are discussed above. Stewart teaches an edible

sheet that includes printing of an edible fluid. Carden teaches bioactive fluids can be dispensed from printers onto substrates.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to print a bioactive fluid on an edible sheet that further includes writing or a message that is achieved with edible colored ink.

One of ordinary skill in the art would have been motivated to do this to produce a product that delivers precise amounts of the bioactive fluid that are specific to the prescription required for a particular patient or application and is delivered in a manner that achieves the best desired results.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 74 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carden in combination with Stewart in further combination with McHugh et al. (US 6027758). The teachings of Carden and Stewart are discussed above. Carden and Stewart do not expressly teach that the ingestible film includes restructured fruit or vegetable material. Stewart does teach that the ingestible films taught in the reference can include a flavoring agent.

McHugh teaches a method of restructuring fruit and vegetables to create a product by itself as a film or as a flavoring agent for various additional products (Col. 3, lines 25-33, 63-67; Col. 4, lines 1-13).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to add a restructured fruit or vegetable to the ingestible films as a flavoring agent.

One of ordinary skill in the art would have been motivated to do this to provide a pleasant taste for the host to which the ingestible film is administered.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed February 19, 2004 have been fully considered but they are not persuasive. Applicants' argue that the Carden and Stewart references do not disclose, teach, or suggest activating a fluid ejector to eject at least one drop of a bioactive fluid in a two-dimensional array onto an ingestible sheet; and forming an array of bioactive deposits on the ingestible sheet. More specifically, applicants argue that the Carden reference teaches a composition that is surgically implanted in the form of metal tubes, rods, or sheet as the substrate material for the invention wherein the sheet is a plastic or biodegradable plastic. Further, applicants argue that Carden is silent on using ingestible films and therefore no motivation exists to combine the teachings of Carden and Stewart. Still further, it is argued that no reasonable expectation of success exists by combining the cited art.

It is the position of the Examiner that the prior art does teach activating a fluid ejector to eject at least one drop of a bioactive fluid in a two-dimensional array onto an ingestible sheet; and forming an array of bioactive deposits on the ingestible sheet.

First, Carden teaches that a bioactive fluid is deposited on a biodegradable sheet. This biodegradable sheet is defined as degradable by the body by solubilization, by macrophage activity or by other naturally present digestive processes. The instant Specification defines an ingestible sheet as substrates that dissolve or degrade in body fluids and/or enzymes. It would appear that the prior art meets such a definition when it defines its sheet as degradable by the body by solubilization, by macrophage activity or by other naturally present digestive processes. Therefore, applicants' arguments to the contrary are unpersuasive.

Second, Carden teaches that the bioactive fluid can be distributed on the substrate is a pattern and that the deposition of the fluid on the substrate can be varied in position as well as amount of the fluid (Col. 6, lines 1-20). Therefore, it is the position of the Examiner that it would have been obvious to one of ordinary skill in the art to vary both the position and the amount of the bioactive at each position. These are limitations that would be routinely determined by one of ordinary skill in the art, through minimal experimentation, as being suitable, absent the presentation of some unusual and/or unexpected results. The results must be those that accrue from the specific limitations.

Third, Carden further teaches that a printhead or fluid ejector is activated (Col. 5, lines 25-44). The invention includes a microprocessor that controls the *firing action of the printhead*. Therefore, again, the reference teaches *activating* a fluid ejector to eject at least one drop of a bioactive fluid in a two-dimensional array onto an ingestible sheet; and forming an array of bioactive deposits on the ingestible sheet. Printhead firing is controlled to deposit a bioactive fluid on a sheet that is biodegradable in various

patterns and with various amounts of the active. The Examiner fails to see how the instant claims are distinguishable over the prior art.

Further, proper motivation does exist to combine the references. The primary reference teaches a bioactive fluid being deposited on a sheet that is degradable by the body by solubilization, by macrophage activity or by other naturally present digestive processes through the use of an ink jet cartridge. The secondary reference teaches one such sheet that can be printed on for ingestion. Therefore, the primary reference teaches the use of a sheet and the secondary reference teaches one such sheet. Further, if the references are combined in reverse, Stewart teaches a sheet that is ingestible wherein a pattern can be printed on it through ink jet printing processes. Carden teaches that active agents can be deposited on degradable sheets through a similar or the same process. It would be obvious to use the sheet of Stewart in the Carden reference. It would also be obvious to add an active agent to the sheets of Stewart. One would be motivated to do so to produce a product that delivers precise amounts of the bioactive fluid that are specific to the prescription required for a particular patient or application and is delivered in a manner that achieves the best desired results.

Therefore, the rejections put forth in the October 22, 2003 Office Action are maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (571) 272-0597. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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